

### REMARKS

Reconsideration and allowance of all claims is respectfully requested.

The above amendments to the Specification and the attached replacement drawing sheets address the "New Matter" issues on page 3 of the office action. Withdrawal of the new matter objection/rejection is respectfully requested.

#### Claims 3 and 4 are patentable under 35 U.S.C. 112, first paragraph.

Withdrawal of the rejection of Claim 3 is respectfully requested. The subject matter of claim 3 is shown in Figures 1-3, particularly Figure 2. The Specification has been amended as above and antecedence for the amendment can now be found in the original Figure 2. No new matter has been added by the amendment. No new issues are raised by the amendment.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph is not understood because it does not contain the amendment referenced in the office action (page 4). The Examiner explains in the Advisory Action that the rejection of claim 4 in the office action page 4, paragraphs 4-5 is correct. In that office action the Examiner states that claim 4 contains the amendment "wherein the cap no longer abuts the tops of the pressurized canister or the means for engagement with the bottom end of the pressurized canister when the cap is in its open position." Applicant has reviewed claim 4 in the previous Response as well as above and does not find such an amendment in the claim. Examiner is again requested to clarify this rejection. It therefore appears that allowable Claim 4 is independent and should be allowed without any rewriting.

Applicant appreciates the indicated allowability of claims 4, 5, 9, and 14-16.

Reconsideration and allowance of the remaining claims are requested.

**Claims 1 - 3, 6 - 8, and 10 - 13 are patentable under 35 U.S.C. 103(a) over Bruna (5,692,492) in view of Rand et al. (6,360,739).**

The present invention defines an inhaler device (1) for dispensing contents from a pressurized canister (6), comprising a mouthpiece (5) arranged in a housing (2), wherein the housing (2) substantially encloses the pressurized canister (6). The claims further describe a lever arm (8,77) comprising means (16) for engaging a bottom of the pressurized canister (6) such that the lever arm (8,77) may be activated by a user in order to dispense a dose. The lever arm (8,77) further engages a yoke (15,79) wherein transfer of movement from said lever arm (8,77) due to activation of said lever arm to the yoke (15,79) is linear and/or non-linear, and that the yoke (15,79) comprises means (44,80) for transferring the movement to a dose counting mechanism arranged in the housing.

Applicant objects to the Examiner's statement on page 8 of the office action that "applicant admits on page 12, lines 4-5 in the [previous] response filed 7/7/08 that 'the dose counting mechanisms are generally interchangeable with minor mechanical modifications.'" That statement in applicant's Response was specifically made with respect to the claimed invention and the disclosed dose counting mechanisms in Applicant's present application vis-à-vis the drawings shown of the various embodiments in the present application. Nothing in Applicant's response suggests, indicates, or even remotely hints at the interchangeability being disclosed by any reference on or off the record.

Bruna relates to a device in which the cover 6 is attached to the bottom of a cylinder 22 in side which the tank is held. Bruna expressly provides an electrical actuation device and points out that mechanical actuators do not work. The cover 6 in Bruna when opened triggers the electrical actuation by means of the spring 8 on the bottom of the tank in the cylinder 22. Bruna

has nothing to do with a lever arm coupled to a yoke that translates a user's movement to the yoke and simultaneously actuates the means for engaging and the means for transferring thereby providing the required dosage in that one simple movement of the lever. The Examiner relies on Rand as teaching dose mechanisms. However, Bruna teaches away from mechanical actuation (see columns 1-3) thereby leading one of ordinary skill in the art away from the mechanical Rand device. Given that inherent guidance to not rely on devices such as that of Rand, the two teachings cannot be combined in the manner proposed by the Examiner,

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

Bruna differs from the present invention as already explained above. Furthermore the dose counting mechanism according to Rand, does not utilise a yoke, so even if the skilled person would modify the Bruna device and combine that with the teachings from Rand, the resultant device would not have anything to do with the claimed invention.

The present invention, due to its inventive construction, utilising a yoke, and the manner in which it is integrated into the housing, provides a device which is different from the suggested devices or even the comparable components of the suggested devices, such that it is not realistic that the proposed device would be anticipated by combining the available prior art.

The Examiner allows that Bruna does not teach or suggest yoke means for transferring movement to a dose counting mechanism arranged in the housing as claimed in Claims 1 - 2, 6 -

8, and 10 - 13. Furthermore, the Examiner does not argue that Rand supplies this yoke means that is lacking in Bruna. In fact, it does not. The yoke means, for example of Figures 17 and 18, is quite unique and unlike anything in the references. The Examiner also does not argue that Rand supplies the elements of Claim 3 that are missing from Bruna. Bruna and Rand, taken alone or in combination, do not teach or suggest each and every claim limitation. Dependent claims 2, 6 - 8, and 10 - 13 depend from independent and patentable Claims 1 and 3 and add further patentable limitations.

Claim 3 as amended distinguishes from Bruna at least in that it teaches that the cap no longer abuts the top of the pressurized canister or the means for engagement with the bottom end of the pressurized canister when the cap is in its open position. This is a result of the very different construction of the present invention from Bruna. Also Bruna's housing encloses the tank and the cover 6 has nothing to do with the tank. Contrastingly in the present invention the cover encloses the top end of the canister when closed.

Claim 6 depends from and shares the patentable features of Claim 3 and adds a lever arm that is flush with or contained in the housing when the cap is closed and projects from the housing when the cap is opened. In claim 6, the Examiner interprets the cap 6 (see fig 1-4) as a section of the housing. It is however clear, especially from fig. 1 and 4 that the housing (which encloses the canister) is not integral or part of the cap, but the cap is an "extra" part of the housing. It is therefore believed that the interpretation by the Examiner is improper. From Fig. 7 and 8 this becomes even more evident. The "lever arm" of Bruna always extends from the housing, whether the cap/lever is open or closed.

In fact the Examiner admits in the office action, on page 6, lines 8-10:

**“However, the Bruna et al., reference lacks yoke means for transferring movement to a dose counting mechanism arranged in the housing as claimed in claims...”**

**The Examiner further states that Rand is being relied on for a metered dose inhaler, meaning Rand is not being relied on for the yoke means.**

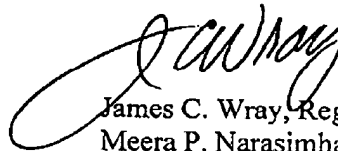
Thus, the Examiner concedes that applicant's invention is novel, unique, non-obvious, and patentable over Bruna and Rand, either singly or in combination.

For at least the above reasons, the rejection of Claims 1 - 3, 6 - 8, and 10 - 13 under 35 U.S.C. 103(a) over Bruna in view of Rand is improper and should be withdrawn.

#### CONCLUSION

Reconsideration and allowance of all claims are respectfully requested.

Respectfully,



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